

Remarks

Entry of the following response, as well as reconsideration and withdrawal of the rejections of record, is respectfully requested.

Arguments presented in the Amendment dated October 30, 2008, in the Response dated June 18, 2008, and in the Amendment dated May 27, 2009, are incorporated herein in their entireties.

Summary of Status of Amendment and Office Action

Entry of this Amendment after final rejection is respectfully requested. In the present amendment, claims 8, 10, 12, 15-17, 25, 26 and 28 are amended, claims 9, 18 and 27 are canceled, and no claim is added. Therefore, claims 8, 10-12, 15-17, 19-22 24-26 and 28 are pending in the application.

In the non-final Office Action dated September 3, 2009, claims 8-12, 15-22 and 24-26 are rejected under 35 U.S.C. § 103 as obvious over Fahrig et al. (WO 96/23506, English Translation).¹ Claims 8-12, 15-22 and 24-28 are also rejected under 35 U.S.C. § 112 as indefinite.

In the present Amendment, claim 8 is amended to remove the term “5-substituted nucleoside” and to incorporate the subject matter of claim 9, which is canceled. The remaining claim amendments are intended to conform the claims with amended claim 8. It is respectfully submitted that the present Amendment introduces no new matter into the claims.

¹ The final Office Action rejects claims 8-12, 15-22 and 24-26 under 35 U.S.C. § 103(a), and does not reject claims 27 or 28 on this basis. Because rejected claims 18 and 19, respectively, depend from non-rejected claims 27 and 28, it is assumed that the Office Action intended to reject claims 27 and 28 on this basis as well, and that the omission of these claims from the obviousness rejection was a typographical error.

Entry of this Amendment after final rejection is appropriate, because the Amendment incorporates claim 9 into claim 8, cancels other claims, and is being made to put the claims into allowable form as indicated by the Examiners during telephone interviews that will be discussed below.

Summary of Interviews

Applicants thank Examiners Jiang and Henry for the courtesy of telephone interviews conducted on November 17, 2009 and December 1, 2009, with Applicants' representatives Arnold Turk and Paul Braier.

During the November 17, 2009 interview, Applicants' representatives emphasized the arguments presented in the previous responses, contended that a *prima facie* case of obviousness had not been established, and that, regardless, unexpected results are sufficient to overcome any such rejection. The Examiners indicated that they would reconsider Applicants' arguments and would follow up in another interview scheduled for December 1, 2009.

During the interview of December 1, 2009, the Examiners indicated that independent claim 8 would be considered to be patentable over the prior art of record if amended to recite administration of the 5-substituted nucleoside during the cytostatic chemotherapy cycle such as recited in dependent claim 9.

The Rejection Of Claims under 35 U.S.C. §103(a) Should be Reconsidered and Withdrawn

Claims 8-12, 15-22 and 24-28 are rejected under 35 U.S.C. § 103(a) as obvious over Fahrig et al. (WO 96/23506, English Translation). Further to the interviews of November 17 and December 1, 2009, and further to the Responses filed May 27, 2009 and November 26, 2007 (which Responses are incorporated by reference herein in their entireties), the claims recite subject matter that the Examiners have indicated to be allowable.

Accordingly, Applicants respectfully request that the rejections of record be reconsidered and withdrawn, and that a Notice of Allowance be promptly sent.

The Rejection Of Claims under 35 U.S.C. § 112

Claims 8-12, 15-22 and 24-28 are rejected under 35 U.S.C. § 112, asserting that it is not clear how a 5-substituted nucleoside can “comprise” (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) rather than “being” (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU).

The present Amendment deletes the term “5-substituted nucleoside” as used to describe the administered compound (or mixture thereof), and replaces it with the term “BVDU, salt, prodrug, or mixtures thereof” or equivalent language. Accordingly, it is respectfully submitted that this rejection is moot, and should be withdrawn.

Nevertheless, Applicants repeat that they do not agree that the rejected language is in any way indefinite. As originally presented, and as discussed in the specification, the 5-substituted nucleoside can comprise a single compound, or can comprise a mixture of compounds. For example, the 5-substituted nucleoside can comprise BVDU, can comprise a salt of BVDU, can comprise a prodrug (such as recited in claims 15 and 27), or can comprise a mixture of two or more compounds, e.g., a mixture comprising one, two, or more of the recited compounds. The rejected language is not indefinite, and Applicants expressly reserve the right to prosecute the canceled subject matter in another application, e.g., a continuation application.

Conclusion

For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention. Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,
Rudolf FAHRIG et al.

Donald L. Day / Paul H. Brenor
Neil F. Greenblum #472,357
Reg. No. 28,394

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191